Foldable Hydrophobic Acrylic UV Absorbing Posterior Chamber Intraocular Lens

xact®
THE LENS

Caution: Federal (U.S.A.) Law restricts this device to sale by, or on the order of a physician.
Manufactured in the U.S.A. •
Advanced Vision Science, Inc.® • Goleta, CA 93117, U.S.A.
Tel 805-683-3851 • Tel 800-235-5781 • Fax 805-964-3065

CE
0459

AVS
Advanced Vision Science, Inc.®

280413 (K.Draft)

DEVICE DESCRIPTION

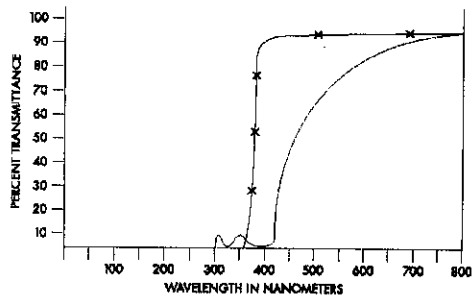
Advanced Vision Science (AVS) foldable lenses are ultraviolet-absorbing posterior chamber intraocular lenses. They are designed to be positioned posterior to the iris where the lens replaces the natural crystalline lens of the eye and functions as a refracting medium in the correction of aphakia. However, accommodation will not be replaced. The optical portion of the lens can be folded prior to insertion.

The physical properties of the AVS Foldable IOL are as follows:

MODEL	Body Diameter (mm)	Total Diameter (mm)
X-60	6.0	12.75
X-70	7.0	13.2

- Lens Configuration: Biconvex optic, 3-piece lens, 7° haptic angulation
- Optic Material: Hydrophobic acrylic
- Power: 10 D to 25D in 0.5 D increments, and in 1.0 D increments from 26.0 to 27.0 D
- Index of Refraction: 1.54 @ 35°C
- Haptic Material: Polyvinylidene fluoride
- UV Transmittance 10% cutoff: For a 20.0 D IOL, 10% transmission at 368 nanometers
- Suggested A-Constant: 118.9*
- Anterior Chamber Depth: 5.5*
- Surgeon Factor: 1.75*

*See the LENS POWER CALCULATIONS section for more information about lens constants and calculation of lens power.



53-Year-Old Human Crystalline Lens (Boettner and Wolter, 1962) ——x—— 20.0 Diopter IOL: 10% transmittance at 368 nanometers
Note: Light transmittance values for an IOL material may vary slightly depending on the method of measurement.

INDICATIONS

The XACT® Foldable Hydrophobic Acrylic Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens is indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed by an extracapsular cataract extraction method. The lens is intended for placement in the capsular bag

WARNINGS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

PRECAUTIONS

- Do not attempt to resterilize the lens as this can produce undesirable side effects.
- Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
- Do not store the lens at a temperature greater than 43°C (110 °F). DO NOT FREEZE. Do not autoclave the intraocular lens.

CLINICAL INVESTIGATIONS

A clinical study of the AVS Model X-60 IOL began in the United States on May 8th, 2002. A total of 383 subjects were enrolled, and 367 subjects were available for examination at one year, 312 were available at two years, and 281 were available at three years. The Model X-70 IOL is a minor modification of the parent Model IOL (X-60) and did not warrant additional clinical testing.

Table 1 displays demographic information of subjects enrolled in the clinical trial. Table 2 summarizes the best-corrected distance visual acuity (BCVA) results for best case subjects (those without clinically significant pre-operative pathologies or macular degeneration at any time during the clinical trial).

ADVERSE EVENTS

Potentially sight threatening adverse events are listed in Table 3, along with the rate of occurrence in the clinical trial of the AVS X-60 IOL, and are compared to the FDA Grid of Historical Controls. The number of patients included in the analysis of both cumulative and persistent adverse events in some cases was less than the number of patients who returned for examination and were available for analysis as a result of missing information in certain fields on the case report forms.

The results of clinical investigations provide reasonable assurance that the AVS X-60 IOL is safe and effective for the visual correction of aphakia following cataract extraction.

CLINICAL TABLES

TABLE 1: SUBJECT DEMOGRAPHICS

	n	%
Number of Subjects	383	100.0%
Gender		
Male	152	39.7%
Female	231	60.3%
Race		
Black	8	2.1%
Caucasian	373	97.4%
Hispanic	2	0.5%
Age		
< 60	43	11.2%
60 to <70	105	27.2%
70 to <80	177	46.2%
≥ 80	58	15.4%
Mean ± SD	71.0 (9.11)	
Range (Min , Max)	45, 93	

25

TABLE 2: VISUAL ACUITY IN BEST CASE POPULATION

Visual Acuity	1 Year		2 Years		3 Years	
	n	%	n	%	n	%
20/20 or better	209	65.3	163	60.8	167	72.2
20/25 or better	275	85.9	215	80.2	203	86.3
20/30 or better	307	95.9	239	89.2	221	92.7
20/40 or better	317	99.1	253	94.4	229	95.1
FDA Grid for % of 20/40 or better	96.7%		N/A		N/A	
N	320		268		242	

TABLE 3: CUMULATIVE AND PERSISTENT ADVERSE EVENTS

Adverse Events	1 Year		FDA Grid 1 Year	2 Years		3 Years	
Cumulative Safety Events **Number of Eyes with Postop Visits=382**	**n/N**	**%**	**%**	**n/N**	**%**	**n/N**	**%**
Endophthalmitis	0/382	0.0%	0.1%	0/382	0.0%	0/382	0.0%
Hyphema	0/382	0.0%	2.2%	0/382	0.0%	0/382	0.0%
Hypopyon	0/382	0.0%	0.3%	0/382	0.0%	0/382	0.0%
IOL Dislocation	0/382	0.0%	0.1%	0/382	0.0%	0/382	0.0%
Cystoid Macular Edema	3/376	0.8%	3.0%	3/377	0.8%	3/377	0.8%
Pupillary Block	0/382	0.0%	0.1%	0/382	0.0%	0/382	0.0%
Retinal Detachment	3/376	0.8%	0.3%	4/377	1.1%	4/377	1.1%
Secondary Surgical Intervention	1/382[1]	0.3%	0.8%	1/382	0.3%	3/382[2,3]	0.8%
Persistent Safety Events	**n/N**	**%**	**%**	**n/N**	**%**	**n/N**	**%**
Number of Eyes Available at the Visit	**367**			**312**		**281**	
Corneal Edema	0/366	0.0%	0.3%	0/312	0.0%	0/281	0.0%
Iritis	1/366	0.3%	0.3%	0/312	0.0%	0/281	0.0%
Cystoid Macular Edema	0/364	0.0%	0.5%	0/309	0.0%	0/280	0.0%
Raised IOP Requiring Treatment	0/366	0.0%	0.4%	0/312	0.0%	0/281	0.0%

[1]IOL was exchanged due to patient complaint of blurred vision, despite good BCVA. Investigator suspected glistenings might be related, however only modest improvement of vision was achieved after IOL exchange.
[2]IOL with glistenings was exchanged during retinal surgery to improve fundus visualization by the surgeon. Loss of vision was the result of retinal pathology and was not associated with the IOL.
[3]IOL was exchanged due to patient complaint of blurred vision. Investigator suspected glistenings might be related, however vision did not improve after IOL exchange. Since vision did improve after subsequent Nd:Yag capsulotomy, the complaint of blurred vision was not associated with the IOL.

27

OTHER CLINICAL FINDINGS

In the IDE clinical trial, "glistenings" were observed in some cases. Glistenings, known to sometimes occur in some other hydrophobic acrylic IOLs, are microscopic vacuoles within the optic of the IOL that are visible through the slit lamp as multiple small refractile specks. Analysis of the clinical data confirmed no effect of glistenings on visual outcomes.

Testing established that glistenings were eliminated by a change in the IOL hydration solution from 10.0% saline to 0.9% saline. This was confirmed in an additional clinical trial conducted outside of the United States. In this study, 172 eyes of 142 patients were examined at least once between 1 and 6 months, and 123 eyes of 101 patients were examined at least once between 6 months and 2 years. No glistenings were observed at any time.

DIRECTIONS FOR USE

1. Prior to implanting, examine the lens package for type, power, and proper configuration.
2. Open the peel pouch and remove the vial in a sterile environment.
3. Remove the lid from the vial.
4. With a pair of smooth forceps, remove the lens from the vial by gently grasping the lens haptic.
5. Rinse the entire lens with sterile balanced salt solution or sterile normal saline.
6. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
7. The lens may be soaked in sterile balanced salt solution until ready for implantation.
8. Place the lens on a flat surface with the correct side uppermost--the tips of the haptics should be pointing in an anti-clockwise direction.
9. With a standard IOL folding forceps, line up the center of the lens at the 3 o'clock to 9 o'clock positions with the centering lines of the folding instrument. Fold the lens so that the optic center moves upward until folded.
10. Using standard IOL insertion forceps, grasp the lens by the optic. Note: please refer to the Directions For Use that are provided with the IOL folding and insertion forceps for additional information.
11. Insert the lens into the capsular bag.

Caution: Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.

LENS POWER CALCULATIONS

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

- Hoffer K J. The Hoffer Q formula: a comparison of theoretic and regression formulas, Journal of Cataract and Refractive Surgery Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.
- Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, Ruiz RS. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
- Norrby NES. Unfortunate Discrepancies, Letter to the Editor and Reply by Holladay JT. Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998.
- Olsen T, Olesen H, Thim K, and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992.
- Retzlaff JA, Sanders DR, Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery, Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990.
- Haigis W: The Haigis Formula. In: Intraocular lens power calculations. H. John Shammas (eds), Slack Incorporated, Thorofare, NJ, USA, pp. 39-57, 2004.

The recommended A-constant on the outside of the box and other lens constants listed in the PRODUCT DESCRIPTION section are intended for use with axial length measurements obtained by applanation A-scan biometry. Use of axial length measurements by optical coherence biometry (i.e. IOL Master) will normally require a different lens constant.

In Table 4, the manufacturer has listed additional recommended lens constants suitable for IOL Master biometry. These values, like those for applanation biometry, are only estimates and are a suggested starting point for use prior to individual optimization by each surgeon. These values do not guarantee an ideal refractive outcome in every patient. Physicians requiring additional information on calculating lens power may contact Advanced Vision Science.

TABLE 4: RECOMMENDED LENS CONSTANTS

Formula	Lens Constant	Applanation Biometry	IOL Master Biometry
Holladay 1	sf	1.75	1.97
SRK/T	A- Const	118.9	119.3
SRK II	A- Const	119.3	119.6
Hoffer Q	pACD	5.5	5.73
Haigis	a0 a1 a2	1.25 0.40 0.10	1.48 0.40 0.10

PATIENT REGISTRATION SECTION

- Advanced Vision Science has established a patient registration system that will allow contact to be made with physicians or patients in the future if unrecognized long-term effects of the lenses are discovered.
- The lens package contains product identification labels for maintaining a record of lens usage and patient registration. At the time of surgery, the prepaid implant registration card is to be completed and returned to Advanced Vision Science for all lenses implanted, returned, destroyed or lost. This implant registration card is to assure lens traceability directly to the implanted patient or to any other disposition of the lens. Advanced Vision Science will maintain this record to monitor the long-term effects of implantation of the lens. It is critical that registration be completed for all patients at the time of surgery.
- An implant identification card is also included in the package. This must be given to the patient. The patient should be instructed to keep the card as a permanent record of his/her implant. The patient should also be instructed to show the card to any eye care practitioner he or she may see in the future.

REPORTING

- Adverse events and/or potentially sight threatening complications that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or degree of incidence should be reported to Advanced Vision Science.
  Office: 805-683-3851, fax: 805-964-3065
- This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

HOW SUPPLIED

The lens is supplied sterile in a screw-cap vial (containing a 0.9% saline solution), within a peel pouch. The package is Gamma Sterilized and should be opened only under sterile conditions.

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

RETURN/EXCHANGE POLICY

Please contact Advanced Vision Science regarding lens return or exchange: Office: 805-683-3851, Fax: 805-964-3065.

SYMBOLS USED ON LABELING

SYMBOL ENGLISH		SYMBOL ENGLISH	
IOL	Intraocular Lens		Do Not Reuse
PC	Posterior Chamber		Use By (YYYY-MM: year-month)
PCL	Posterior Chamber Lens		Gamma Sterilized
UV	Ultraviolet	SN	Serial Number
D	Diopter		See Instructions for Use
ØB	Body Diameter (Optic Diameter)		Storage Temperature Limitation
ØT	Overall Diameter (Overall Length)	PVDF	Polyvinylidene Fluoride